



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

David B. Quick
ICE MILLER LLP
One American Square
Suite 2900
Indianapolis, IN 46282-0200

DEC 29 2008

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,919,140

Dear Mr. Quick :

An interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,919,140 for a period of 1 year. A copy of the Federal Register notice published in accordance with 35 U.S.C. 156(d)(5)(B) on October 20, 2008 at 73 Fed. Reg. 62260 is enclosed herewith. While a courtesy copy of this letter and the application for interim extension is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to patent expiration dates.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: Andara™ OFS™ System
FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Purdue Research Foundation
Request for Patent Term Extension
U.S. Patent No. 4,919,140

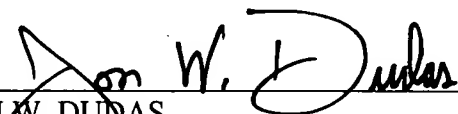
:
: **ORDER GRANTING**
: **INTERIM EXTENSION**

On September 29, 2008, the patent owner, Purdue Research Foundation, timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,919,140. The patent claims the medical device known as Andara™ OFS™ System and a method of using the Andara™ OFS™ System. The application indicates that a Humanitarian Device Exemption, HDE 070002, for the medical device Andara™ OFS™ System has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the expiration date of the patent (October 14, 2008), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,919,140 is granted for a period of one year from the expiration date of the patent, i.e., until October 14, 2009.

October 14, 2008
Date



JON W. DUDAS
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office